IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Robert A. Rabiner et al.	Art Unit	: 3737
Serial No.	: 10/774,898	Examiner	: Peter Luong
Filed	: February 9, 2004	Conf. No.	: 8765
Title	: APPARATUS AND METHOD FOR AN ULTRASONIC MEDICAL DEVICE OPERATING IN TORSIONAL AND TRANSVERSE MODES		

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BRIEF ON APPEAL

Applicants are appealing the final rejection of claims 1, 3-24, 26-34, 36-55, 57-61, and 75-86. Applicants request that the rejection of these claims be reversed. A notice of appeal was filed on May 9, 2008.

(1) Real Party in Interest

The real party in interest is Omnisonics Medical Technologies, Inc.

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 2, 25, 35, 56, and 62-74 are cancelled.

Claims 1, 3-24, 26-34, 36-55, 57-61, and 75-86 stand rejected and are under appeal.

(4) Status of Amendments

All amendments have been entered.

(5) Summary of Claimed Subject Matter

This invention generally relates to medical devices and related methods. Claims 1, 24, 34, and 55 are independent claims.

Claim 1 features an ultrasonic medical device that includes a transducer coupled to an ultrasonic probe. The transducer is configured to create a torsional vibration along the probe, and the probe and the transducer are adapted so that the torsional vibration induces a transverse vibration along a portion of the probe.

Claim 1 reads as follows:

1. An ultrasonic medical device comprising:

an ultrasonic probe comprising a proximal end, a distal end and a longitudinal axis therebetween; and

a transducer coupled to the ultrasonic probe, the transducer being configured to create a torsional vibration along the ultrasonic probe, the ultrasonic probe and the transducer being adapted so that the torsional vibration induces a transverse vibration along a portion of the ultrasonic probe.

Claim 24 features a medical device that includes a transducer coupled to an elongated, flexible probe. The transducer is configured to create a torsional vibration along the longitudinal axis of the probe, and the probe and the transducer are adapted so that the torsional vibration induces a transverse vibration along the longitudinal axis of the probe.

Claim 24 reads as follows:

24. A medical device comprising:

an elongated, flexible probe comprising a proximal end, a distal end and a longitudinal axis between the proximal end and the distal end;

a transducer coupled to the elongated, flexible probe, the transducer being configured to create a torsional vibration along the longitudinal axis of the elongated, flexible probe when electrical energy is applied to the transducer, the elongate, flexible probe and the transducer being adapted so that the torsional

vibration induces a transverse vibration along the longitudinal axis of the elongated, flexible probe.

Claim 34 features a method that includes producing a torsional vibration along an ultrasonic probe. The torsional vibration induces a transverse vibration in a portion of the probe.

Claim 34 reads as follows:

34. A method comprising:

moving an ultrasonic probe to a treatment site in a body such that the ultrasonic probe is in communication with a biological material; and

producing a torsional vibration along the ultrasonic probe, the torsional vibration inducing a transverse vibration in a portion of the ultrasonic probe.

Claim 55 features a method that includes producing a torsional vibration along a portion of a flexible probe. The torsional vibration induces a transverse vibration along the longitudinal axis of the probe.

Claim 55 reads as follows:

55. A method comprising:

placing an ultrasonic probe in communication with a biological material in a body; and

activating an energy source to produce an electric signal that drives a transducer coupled to the ultrasonic probe to produce a torsional vibration along a portion of the flexible probe, the torsional vibration inducing a transverse vibration along the longitudinal axis of the flexible probe.

Referring to Fig. 1 of Applicants' application, which is reproduced below, an embodiment of Applicant's claimed device includes an ultrasonic probe 15 that is coupled to a generator 99 via a transducer. See, e.g., Application, p. 7, lines 13-18. A handle 88 surrounds the transducer. See, e.g., id., lines 15-18.

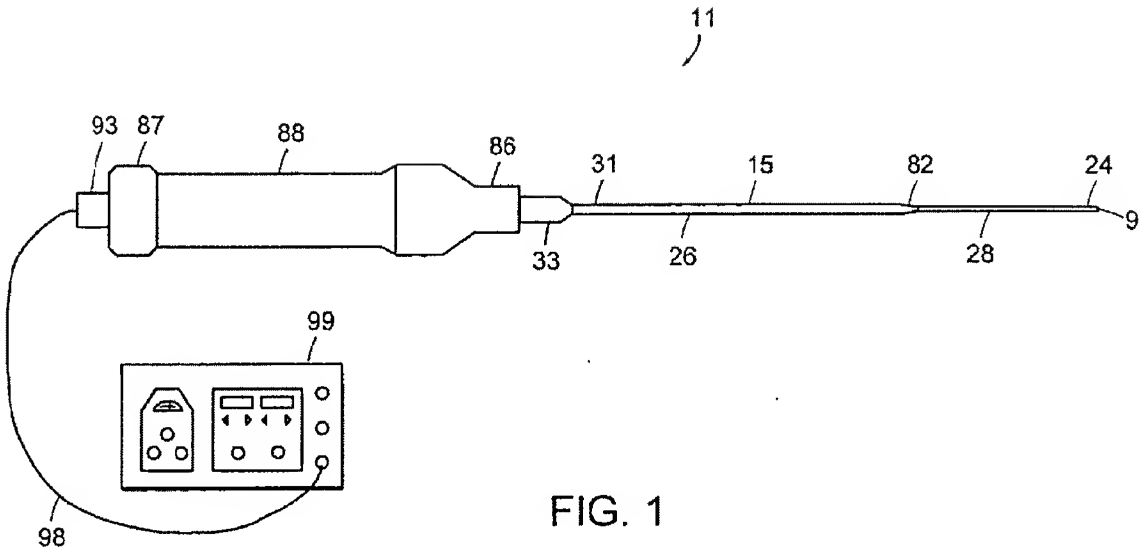

FIG. 1

During use, the transducer converts electrical energy provided by generator 99 to mechanical energy to create a torsional wave along the longitudinal axis of ultrasonic probe 15, causing ultrasonic probe 15 to vibrate in a torsional mode with a torsional vibration. See, e.g., id., p. 11, line 27 – p. 12, line 11. The torsional wave transmitted along the longitudinal axis of ultrasonic probe 15 produces a component of force in a transverse direction relative to the longitudinal axis of ultrasonic probe 15, thereby exciting a transverse wave along the longitudinal axis of ultrasonic probe 15. See, e.g., id., p. 12, line 27 – p. 13, line 1. As a result, the torsional vibration induces a transverse vibration along a portion of the longitudinal axis of ultrasonic probe 15. See, e.g., id., p. 13, lines 1-6. The transverse vibration is induced when the frequency of the transducer is close to a transverse resonant frequency of ultrasonic probe 15. See, e.g., id., lines 26-27.

The torsional and transverse vibrations can be superimposed along ultrasonic probe 15, as shown in Fig. 3, or segregated, as shown in Fig. 7. See, e.g., id., p. 16, line 14 – p. 17, line 1.

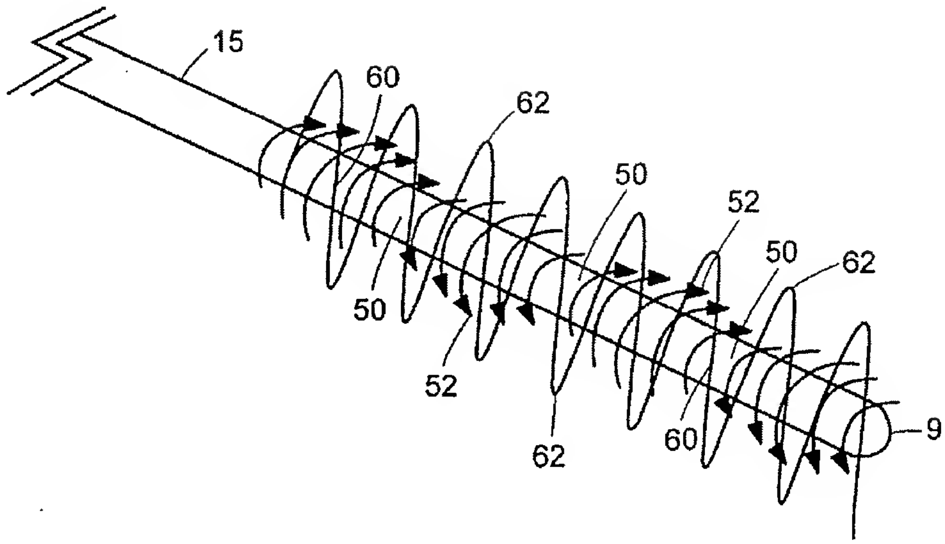

FIG. 3

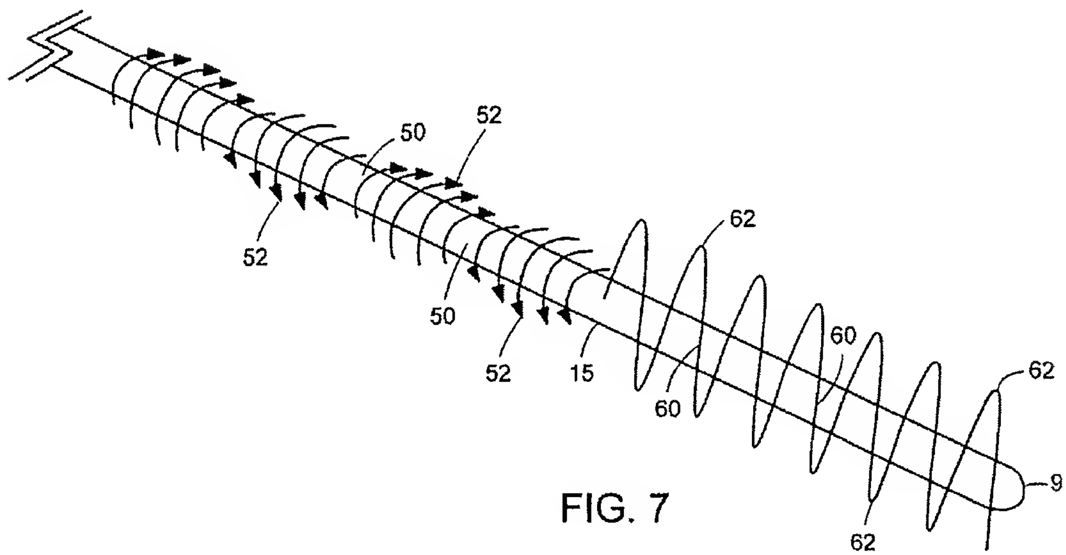

FIG. 7

Certain methods of using Applicants' device include moving ultrasonic probe 15 to a treatment site and placing ultrasonic probe 15 in communication with biological material, and then activating the transducer to produce torsional vibration along the longitudinal axis of ultrasonic probe 15. See, e.g., id., p. 21, line 24 – p. 22, line 3; p. 22, lines 6-10. The torsional vibration induces transverse vibration along a portion of ultrasonic probe 15 to treat or remove the biological material along that portion of ultrasonic probe 15. See, e.g., id., p. 22, lines 3-5

and 10-13. The biological material can, for example, be removed from a region having a radius of about six millimeters around ultrasonic probe 15. See, e.g., id., p. 20, lines 2-7.

(6) Grounds of Rejection to be Reviewed on Appeal

Claims 1, 3-24, 26-34, 36, 40-55, 57-61, and 75-86 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kuris, U.S. Patent 3,565,062 ("Kuris").

Claims 37-39, 57, and 58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuris in view of McCullough (U.S. Patent 6,723,451).

(7) Argument

Claims 1, 3-24, 26-34, 36, 40-55, 57-61, and 75-86 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Kuris, U.S. Patent 3,565,062 ("Kuris"). However, Kuris fails to disclose a device that includes a probe and transducer that are adapted so that a torsional vibration created along the probe induces a transverse vibration along the probe, as required by claims 1, 3-24, 26-33, and 75-80. Similarly, Kuris fails to disclose a method that includes producing a torsional vibration along a probe that induces a transverse vibration along the probe, as required by claims 34, 36, 40-55, 57-61, and 81-86.

Referring to Kuris' Figs. 4 and 6, which are reproduced below, Kuris discloses a device that includes an ultrasonic motor 41 connected to an energy transmission cable 42 having a tool member 43 at its terminal end. Kuris, col. 5, lines 68-74.

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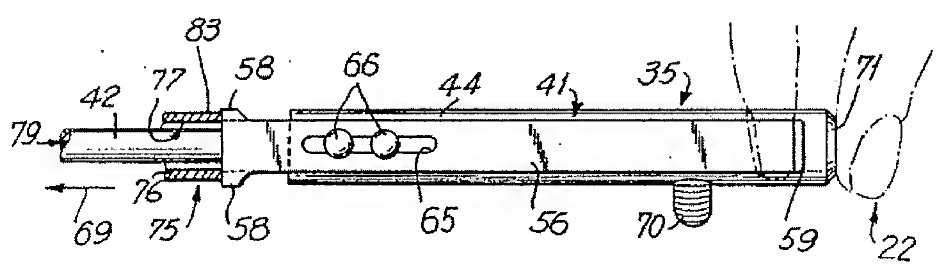
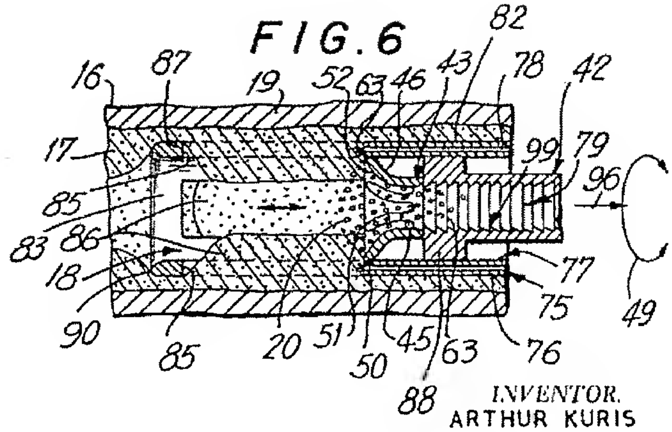


FIG. 6



The Examiner contends that Kuris' ultrasonic motor 41 corresponds to Applicants' claimed transducer and that Kuris' tool member 43 corresponds to Applicants' claimed probe. The Examiner takes the position that Kuris' tool member 43 and ultrasonic motor 41 are "capable of being adapted so that the torsional vibration induces a transverse vibration." Office Action mailed February 12, 2008, p. 2 (emphasis added). In support of this position the Examiner relies on the following passage of Kuris:

> [T]he active tool output surface enjoys transverse vibration, compressional vibration, flexural vibrations or torsional vibrations or even combinations of said vibrations. For instance, torsional and compressional vibration combined, produce a kind of "corkscrew" vibratory motion, which is particularly suitable for obtaining small foreign deposit samples for biopsy purposes. Kuris, col. 4, lines 44-50.

Even assuming that the above-quoted passage can properly be read as disclosing that Kuris' tool member 43 can be vibrated both torsionally and transversely, which Applicants do not concede, Kuris still does not disclose a probe and transducer that are adapted so that a torsional vibration along the probe induces a transverse vibration along his probe, as required by Applicants' claims 1, 3-24, 26-33, and 75-80. As noted above, the Examiner contends that Kuris' tool member 43 and ultrasonic motor 41 are "capable of being adapted so that the torsional vibration induces a transverse vibration." However, Kuris gives no indication that this

is true. Moreover, even assuming that Kuris' tool member 43 and ultrasonic motor 41 are "capable of being adapted so that the torsional vibration induces a transverse vibration," as the Examiner argues, Kuris certainly does not disclose that his tool member and ultrasonic transducer are adapted so that a torsional vibration along his tool member induces a transverse vibration along his tool member. In fact, throughout Kuris' patent, Kuris does not even mention the idea of using a torsional vibration to induce a transverse vibration along a probe.

Similarly, with regard to claims 34, 36, 40-55, 57-61, and 81-86, Kuris fails to disclose producing a torsional vibration along a probe that induces a transverse vibration along the probe. Kuris provides no disclosure, for example, of producing a torsional vibration along his tool member that induces a transverse vibration along his tool member. Kuris, as noted above, does not even mention the idea of using a torsional vibration to induce a transverse vibration along a probe.

Moreover, "[i]n order to anticipate, a prior art reference must not only disclose all of the limitations of the claimed invention, but also be enabled." Elan Pharms., Inc. v. Mayo Found., 346 F.3d 1051, 1054 (Fed. Cir. 2003). "A reference is enabled when its disclosures are sufficient to allow one of skill in the art to make and use the claimed invention." Id., 346 F3d at 1054 (quoting Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1374 (Fed. Cir. 2001). Kuris' disclosure would not enable one of ordinary skill in the art to make and use a device including a probe and a transducer that are adapted so that a torsional vibration along the probe induces a transverse vibration along the probe, as required by Applicants' claims 1, 3-24, 26-33, and 75-80. Nor would it enable one of ordinary skill to produce a torsional vibration along a probe that induces a transverse vibration along the probe, as required by claims 34, 36, 40-55, 57-61, and 81-86. As mentioned above, Kuris does not even disclose the idea of using a torsional vibration to induce a transverse vibration along a probe, let alone provide an enabling disclosure for such a feature.

In view of the foregoing, Applicants request that the rejection of claims 1, 3-24, 26-34, 36, 40-55, 57-61, and 75-86 as being anticipated by Kuris be reversed.

Claims 37-39, 57, and 58 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuris in view of McCullough (U.S. Patent 6,723,451). Kuris fails to disclose or render obvious a method that includes producing a torsional vibration along a probe that induces a

transverse vibration along the probe, as required by claims 37-39, 57, and 58. Kuris, as discussed above, does not even mention the idea of using a torsional vibration to induce a transverse vibration along a probe. McCullough fails to cure these deficiencies of Kuris. Like Kuris, McCullough does not even mention the idea of using a torsional vibration to induce a transverse vibration along a probe. In addition, after reading Kuris and McCullough, one of ordinary skill would not have modified the method of use described in Kuris to include this feature of Applicants' claims. There is simply no indication in Kuris or McCullough that such a modification would be beneficial. Thus, Kuris and McCullough, taken alone and in combination, fail to disclose or render obvious a method that includes producing a torsional vibration along a probe that induces a transverse vibration along the probe. Therefore, Applicants request that the rejection of claims 37-39, 57, and 58 be reversed.

The fee in the amount of $255.00 is being paid herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 28, 2008

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Appendix of Claims

1. An ultrasonic medical device comprising:

an ultrasonic probe comprising a proximal end, a distal end and a longitudinal axis therebetween; and

a transducer coupled to the ultrasonic probe, the transducer being configured to create a torsional vibration along the ultrasonic probe, the ultrasonic probe and the transducer being adapted so that the torsional vibration induces a transverse vibration along a portion of the ultrasonic probe.

3. The ultrasonic medical device of claim 1 wherein the portion of the ultrasonic probe along which the transverse vibration is induced extends along at least a portion of the longitudinal axis of the ultrasonic probe.

4. The ultrasonic medical device of claim 1 wherein tension to the ultrasonic probe tunes the transverse vibration into coincidence with the torsional vibration.

5. The ultrasonic medical device of claim 1 wherein bending the ultrasonic probe tunes the transverse vibration into coincidence with the torsional vibration.

6. The ultrasonic medical device of claim 1 wherein bending the ultrasonic probe shifts a frequency of the ultrasonic probe causing the transverse vibration to coincide with the torsional vibration.

7. The ultrasonic medical device of claim 1 wherein the torsional vibration and the transverse vibration are superimposed along the portion of the ultrasonic probe along which the transverse vibration is induced.

8. The ultrasonic medical device of claim 1 wherein the torsional vibration and the transverse vibration are segregated along the ultrasonic probe.

9. The ultrasonic medical device of claim 1 wherein the torsional vibration of the ultrasonic probe produces a plurality of torsional nodes and a plurality of torsional anti-nodes along at least the portion of the ultrasonic probe along which the transverse vibration is induced.

10. The ultrasonic medical device of claim 1 wherein the torsional vibration of the ultrasonic probe causes a rotation and counterrotation along at least the portion of the ultrasonic probe along which the transverse vibration is induced.

11. The ultrasonic medical device of claim 1 wherein the torsional vibration of the ultrasonic probe is propagated in a forward direction and a reverse direction about a plurality of nodes along at least the portion of the ultrasonic probe along which the transverse vibration is induced.

12. The ultrasonic medical device of claim 1 wherein, during use, the torsional vibration and the transverse vibration generate acoustic energy in a medium surrounding the ultrasonic probe through an interaction of a surface of the ultrasonic probe and the medium surrounding the ultrasonic probe.

13. The ultrasonic medical device of claim 1 wherein the transverse vibration of the ultrasonic probe produces a plurality of transverse nodes and a plurality of transverse anti-nodes along at least the portion of the ultrasonic probe along which the transverse vibration is induced.

14. The ultrasonic medical device of claim 1 wherein, during use, the torsional vibration generates acoustic energy in a medium surrounding the ultrasonic probe.

15. The ultrasonic medical device of claim 1 wherein, during use, the transverse vibration generates acoustic energy in a medium surrounding the ultrasonic probe.

16. The ultrasonic medical device of claim 1 further comprising an acoustic assembly configured to deliver ultrasonic energy in a frequency range from about 10 kHz to about 100 kHz.

17. The ultrasonic medical device of claim 1 further comprising an energy source configured to determine a resonant frequency of the transducer and to provide electrical energy to the transducer at the resonant frequency of the transducer.

18. The ultrasonic medical device of claim 1 wherein the ultrasonic probe has a flexibility allowing the ultrasonic probe to support the torsional vibration and the transverse vibration.

19. The ultrasonic medical device of claim 1 wherein the ultrasonic probe has an approximately circular cross section from the proximal end of the ultrasonic probe to the distal end of the ultrasonic probe.

20. The ultrasonic medical device of claim 1 wherein the ultrasonic probe has a varying diameter from the proximal end of the ultrasonic probe to the distal end of the ultrasonic probe.

21. The ultrasonic medical device of claim 1 wherein a portion of the ultrasonic probe has a radially asymmetric cross section.

22. The ultrasonic medical device of claim 1 wherein the ultrasonic probe has a substantially uniform cross section from the proximal end of the ultrasonic probe to the distal end of the ultrasonic probe.

23. The ultrasonic medical device of claim 1 wherein the ultrasonic probe has a varying cross section from the proximal end of the ultrasonic probe to the distal end of the ultrasonic probe.

24. A medical device comprising:

an elongated, flexible probe comprising a proximal end, a distal end and a longitudinal axis between the proximal end and the distal end;

a transducer coupled to the elongated, flexible probe, the transducer being configured to create a torsional vibration along the longitudinal axis of the elongated, flexible probe when electrical energy is applied to the transducer, the elongate, flexible probe and the transducer being adapted so that the torsional vibration induces a transverse vibration along the longitudinal axis of the elongated, flexible probe.

26. The medical device of claim 24 wherein at least a portion of the longitudinal axis of the elongated, flexible probe supports the torsional vibration and the transverse vibration.

27. The medical device of claim 24 wherein tension to the elongated, flexible probe tunes the transverse vibration into coincidence with the torsional vibration.

28. The medical device of claim 24 wherein the torsional vibration and the transverse vibration are superimposed along the longitudinal axis of the elongated, flexible probe.

29. The medical device of claim 24 wherein the torsional vibration and the transverse vibration are segregated along the longitudinal axis of the elongated, flexible probe.

30. The medical device of claim 24 wherein the elongated, flexible probe has a substantially uniform diameter from the proximal end of the elongated, flexible probe to the distal end of the elongated, flexible probe.

31. The medical device of claim 24 wherein the elongated, flexible probe has a varying diameter from the proximal end of the elongated, flexible probe to the distal end of the elongated, flexible probe.

32. The medical device of claim 24 wherein the elongated, flexible probe is disposable.

33. The medical device of claim 24 wherein the elongated, flexible probe is constructed for a single use on a single patient.

34. A method comprising:

moving an ultrasonic probe to a treatment site in a body such that the ultrasonic probe is in communication with a biological material; and

producing a torsional vibration along the ultrasonic probe, the torsional vibration inducing a transverse vibration in a portion of the ultrasonic probe.

36. The method of claim 34 wherein the portion of the ultrasonic probe in which the transverse vibration is induced supports the torsional vibration and the transverse vibration.

37. The method of claim 34 further comprising tuning the transverse vibration into coincidence with the torsional vibration along the portion of the ultrasonic probe in which the transverse vibration is induced.

38. The method of claim 34 further comprising applying a tension to the ultrasonic probe to tune the transverse vibration into coincidence with the torsional vibration.

39. The method of claim 34 further comprising bending the ultrasonic probe to tune the transverse vibration into coincidence with the torsional vibration.

40. The method of claim 34 further comprising superimposing the torsional vibration and the transverse vibration along the portion of the ultrasonic probe in which the transverse vibration is induced.

41. The method of claim 34 further comprising segregating the torsional vibration and the transverse vibration along the ultrasonic probe.

42. The method of claim 34 wherein the torsional vibration is produced by a transducer coupled to the ultrasonic probe.

43. The method of claim 34 further comprising generating acoustic energy in a medium surrounding the ultrasonic probe through an interaction of a surface of the ultrasonic probe and the medium surrounding the ultrasonic probe resulting from the torsional vibration and the transverse vibration.

44. The method of claim 34 further comprising producing a plurality of nodes and a plurality of anti-nodes along at least the portion of the ultrasonic probe in which the transverse vibration is induced.

45. The method of claim 34 further comprising producing a plurality of transverse nodes and a plurality of transverse anti-nodes along at least the portion of the ultrasonic probe in which the transverse vibration is induced.

46. The method of claim 34 further comprising producing a rotation and counterrotation of the ultrasonic probe along at least the portion of the ultrasonic probe in which the transverse vibration is induced.

47. The method of claim 34 further comprising projecting the torsional vibration in a forward direction and a reverse direction about a plurality of nodes of the ultrasonic probe.

48. The method of claim 34 further comprising sweeping the ultrasonic probe along the treatment site.

49. The method of claim 34 further comprising moving the ultrasonic probe back and forth along the treatment site.

50. The method of claim 34 further comprising rotating the ultrasonic probe along the treatment site.

51. The method of claim 34 further comprising delivering ultrasonic energy to the ultrasonic probe in a frequency range from about 10 kHz to about 100 kHz.

52. The method of claim 42 further comprising determining a resonant frequency of the transducer and providing electrical energy to the transducer at the resonant frequency of the transducer.

53. The method of claim 34 further comprising providing the ultrasonic probe having a flexibility allowing the ultrasonic probe to support the torsional vibration and the transverse vibration.

54. The method of claim 34 wherein the portion in which the transverse vibration is induced extends along at least a portion of the longitudinal axis of the ultrasonic probe.

55. A method comprising:

placing an ultrasonic probe in communication with a biological material in a body; and

activating an energy source to produce an electric signal that drives a transducer coupled to the ultrasonic probe to produce a torsional vibration along a portion of the flexible probe, the torsional vibration inducing a transverse vibration along the longitudinal axis of the flexible probe.

57. The method of claim 55 further comprising applying a tension to the flexible probe causing the transverse vibration to tune into coincidence with the torsional vibration.

58. The method of claim 55 further comprising bending the flexible probe causing the transverse vibration to tune into coincidence with the torsional vibration.

59. The method of claim 55 further comprising superimposing the torsional vibration and the transverse vibration along the longitudinal axis of the flexible probe.

60. The method of claim 55 further comprising segregating the torsional vibration and the transverse vibration along the longitudinal axis of the flexible probe.

61. The method of claim 55 further comprising generating acoustic energy in a medium surrounding the ultrasonic probe through an interaction of a surface of the ultrasonic probe and the medium surrounding the ultrasonic probe resulting from the torsional vibration and a transverse vibration.

75. The ultrasonic medical device of claim 1 wherein the ultrasonic probe has a first region having a first diameter and a second region having a second diameter that is smaller than the first diameter.

76. The ultrasonic medical device of claim 75 wherein the ultrasonic probe has a tapered transition between the first and second regions.

77. The ultrasonic medical device of claim 75 wherein the ultrasonic probe has a third region having a third diameter that is smaller than the second diameter.

78. The medical device of claim 24 wherein the elongate, flexible probe has a first region having a first diameter and a second region having a second diameter that is smaller than the first diameter.

79. The medical device of claim 78 wherein the elongate, flexible probe has a tapered transition between the first and second regions.

80. The medical device of claim 78 wherein the elongate, flexible probe has a third region having a third diameter that is smaller than the second diameter.

81. The method of claim 34 wherein the ultrasonic probe has a first region having a first diameter and a second region having a second diameter that is smaller than the first diameter.

82. The method of claim 81 wherein the ultrasonic probe has a tapered transition between the first and second regions.

83. The method of claim 81 wherein the ultrasonic probe has a third region having a third diameter that is smaller than the second diameter.

84. The method of claim 55 wherein the ultrasonic probe has a first region having a first diameter and a second region having a second diameter that is smaller than the first diameter.

85. The method of claim 84 wherein the ultrasonic probe has a tapered transition between the first and second regions.

86. The method of claim 84 wherein the ultrasonic probe has a third region having a third diameter that is smaller than the second diameter.

Evidence Appendix

None.

Related Proceedings Appendix

None.